PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Form PCT/IPEA/416	
LTP-0015.PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/SE2004/001727	24-11-2004	25-11-2003
International Patent Classification (IPC) or national classification and IPC		
See Supplemental Box		
Applicant		
LTP Lipid Technologies Provider AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 1 sheets, as follows:
      - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22-06-2005	02-03-2006
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Patrick Andersson/Els Telephone No. +46 8 782 25 00

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Cover sheet

International patent classification (IPC)
A61K 9/107 (2006.01)
A61K 31/203 (2006.01)
A61K 38/13 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001727

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____ ,
which is the language of a translation furnished for the purposes of:

☐ international search (Rules 12.3(a) and 23.1(b))

☐ publication of the international application (Rule 12.4(a))

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☐ the international application as originally filed/furnished

☒ the description:

pages 1-21 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* 1 received by this Authority on 23-09-2005

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001727

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4-8, 12	YES
	Claims	1-3, 9-11, 13	NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:
D1: WO00/32219, A1
D2: US2003/0180352, A1

D1 discloses cyclosporine formulations in the same ranges as the present claims. Said formulations are put into gelatine capsules. Some of these are solid at room temperature, see table 1 examples 7, 11 and 13-14.
Consequently, claims 1-3, 9 -11 and 13 lack novelty.

During the preparation of the formulations in D1, ethanol is used as a solvent. The solutions are evaporated to complete dryness. These compositions may contain traces of solvent.

D1 is regarded as being the closest prior art. In D1 the solid lipid material is not preferred; it does not have a positive influence on the food effect. Hence, the positive influence on the food effect shown in the present application can not be attributed to the generalisations in the claims.
Moreover, it is not even ascertained that all formulations in the examples of the application are solid at room temperature, since that property is not reflected on to any extent in the examples or elsewhere in the application. It is instead presented as one option on the same footing as other formulations, such as emulsions.
An inventive step has only been shown for the exact formulations of the examples.

The composition according to the present claims 6 or 12 differs from D1 by having the active ingredient in a particle. This feature is known in the art, see D2. No particular

.../...

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: Box V

advantage in using particles in a lipid material with galactolipids has been shown. The skilled person would therefore regard it as a normal option to include this feature in the composition in D1. Therefore, claims 6 and 12 lack inventive step.

The remaining claims 4-5, 7-8 are considered to involve particular detail executions obvious to a person skilled in the art. Therefore, the invention according to these claims is not considered to involve an inventive step.

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23 -09- 2005

Claims

1. Pharmaceutical composition for oral administration comprising an active substance having a food effect dissolved or dispersed in a lipid material that is solid at room temperature, the lipid material consisting of membrane lipid selected from galactolipid; non-polar lipid selected from mono-, di- and triacylglycerol and mixtures thereof; optionally polar lipid other than membrane lipid; optionally polar solvent.
2. The composition of claim 1, wherein the galactolipid comprises digalactosylglycerol in an amount of not less than 5 % by weight of the lipid material.
3. The composition of claim 1, wherein the lipid material comprises at least 20 % by weight of diglyceride, triglyceride or mixtures thereof.
4. The composition of claim 1, wherein the polar solvent is selected from water, alcohol with up to 8 carbon atoms and from 1 to 3 hydroxyl groups.
5. The composition of claim 4, wherein the alcohol is selected from ethanol, propylene glycol and glycerol.
6. The composition of claim 1, wherein the particle size of the active substance is less than 20 µm.
7. The composition of any of claims 1-6, wherein the active substance is an antiviral.
8. The composition of claim 7, comprising up to 50% by weight of antiviral, from 10% by weight to about 70% by weight of galactolipid; and from 10 to 70 % by weight of monoglyceride.
9. The composition of any of claims 1-6, wherein the active substance is an immunosuppressant.
10. The composition of claim 9, comprising from 0.1 % by weight to 20 % by weight of immunosuppressant, from 1 % by weight to 40 % by weight of galactolipid, and from 5 % by weight to 40 % by weight of monoglyceride.
11. The composition of any of claims 1-5 and 7-10, wherein the active substance is dissolved in the lipid material.
12. The composition of any of claims 1-11 in form of solid lipid particles of a diameter of no more than 20 µ in which the active substance is dissolved or dispersed.
13. A gelatine capsule filled with the composition of any of claims 1-12.

AMENDED SHEET